UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,545	07/16/2003	Lars Olson	1522-1001-1	5943

466 7590 04/16/2007

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/619,545	**Applicant(s)** OLSON ET AL.	
	Examiner Delia M. Ramirez	**Art Unit** 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 24-28.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

ADVISORY ACTION

1. Claims 24-28 are pending.

2. The request for entering amendments to the specification and the claims (amendment of claims 24-26, 28 and cancellation of claims 15-23, 29-32), and arguments filed on 3/16/2007 under 37 CFR 1.116 in reply to the Final Action mailed on 11/16/2006 are acknowledged. The proposed amendments to the specification and the claims will be entered. Objections to the specification are hereby withdrawn by virtue of Applicant's amendment. While the claims as amended would be objected to for the reasons set forth below, the amendments to the claims overcome the double patenting objection, 35 USC 112, second paragraph rejections, the 35 USC 101 non-statutory subject matter rejection, the scope of enablement rejection regarding nucleic acids consisting of two or more of SEQ ID NO: 1-7, and the 102/103 art rejections. Thus, the amendments are deemed sufficient to reduce the number of issues for appeal. However, the proposed amendments to the claims fail to overcome the utility rejection for the reasons of record and those set forth below.

3. Amended claims 25-26 would be objected to due to the recitation of "nucleic acid according to claim 24, wherein the sequence" as there is no explicit antecedent basis for "the sequence". Amending the claims to recite, for example, "nucleic acid according to claim 24, wherein the nucleic acid consists of SEQ ID NO: X", would obviate the objection.

4. Amended claim 28 would be objected due to the recitation of "detecting nucleic acid according to claim 26" for lacking an article next to the term "nucleic acid". It should be amended to recite "detecting the nucleic acid according to claim 26".

5. With regard to the utility rejection, Applicant submits that the substantial utility requirement has been met by the teachings of the specification in that Applicant has disclosed the specific disease that can be detected with the claimed nucleic acids. Thus, Applicant believes that a specific and substantial utility has been disclosed. Applicant also submits that the PTO questions the credibility and operability of the

claimed invention on the grounds that the utility of the invention has been established with statistical evidence and that a consensus does not exist in the art regarding the role of the ADH7 gene in Parkinson's disease. Applicant reminds the Examiner that Applicant is not required to provide evidence sufficient to establish that an asserted utility is a statistical certainty. Applicant maintains that the Tan, Buervenich and Lucentini references, at best, show lack of consensus in the art regarding the role of ADH7 in Parkinson's disease but do not show that Applicant's asserted utility in Parkinson's disease expressely contravenes established scientific principles and beliefs.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. The Examiner acknowledges that Applicant is not required to provide evidence sufficient to establish that an asserted utility is a statistical certainty. However, in the instant case, the Examiner has also provided evidence which completely contradicts Applicant's assertion regarding a link between the disclosed polymorphisms and Parkinson's disease (Tan et al.)

As indicated by the Examiner in the Final action, the Examiner is not contending that Applicant's asserted utility is not specific. Instead, the Examiner has indicated that the asserted utility is not substantial. Therefore, the claimed invention fails to meet the specific *and* substantial utility prong. With regard to credibility, it is reiterated herein that it is not the Examiner's contention that there is categorically no linkage whatsoever between ADH7 and Parkinson's disease, or that the disclosed polymorphisms are absolutely unrelated to Parkinson's disease. Thus, the Examiner is not deeming Applicant's alleged utility as incredible. Instead, the Examiner has repeatedly indicated that in view of the fact that (1) there is evidence in the art (Tan et al.) that specifically addresses Applicant's study and contradicts Applicant's asserted association between the disclosed polymorphisms and Parkinson's disease, and (2) the alleged association was found by statistical correlation, which is shown by Lucentini as not always sufficient to show an association between a polymorphism and disease, one of skill in the art would have to conduct further research to verify whether the disclosed polymorphisms can be used as

asserted. It is noted that Buervenich et al. discloses the same study that Applicant has disclosed in the specification. The inventorship in the instant application comprises all but one of the authors of the Buervenich et al. reference. Therefore, since Applicant has failed to provide any additional evidence which would lead one of skill in the art to conclude that there is a link between the disclosed polymorphisms and Parkinson's disease, such as how these polymorphisms correlate with the symptoms of the disease, or the biological role of such polymorphism in developing the disease, one cannot reasonably conclude that the asserted utility is substantial or well-established.

7. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: NONE

Claim(s) rejected: 24-28

Claim(s) withdrawn from consideration: NONE

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
April 12, 2007